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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09:875,519	06/06/2001	Timothy C. Farries	4-30443B/D1	6920
1095 7	590 09/10/2002			
THOMAS HOXIE NOVARTIS CORPORATION PATENT AND TRADEMARK DEPT			EXAMINER	
			DECLOUX, AMY M	
564 MORRIS A SUMMIT, NJ	- · - · · - · · -		ART UNIT	PAPER NUMBER
			1644	()
			DATE MAILED: 09/10/2002	(1

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	09/875,519	FARRIES ET AL.				
Office Action Summary	Examiner	Art Unit				
•	Amy M. DeCloux	1644				
The MAILING DATE of this communication ap						
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a rep - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut - Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).  Status	136(a). In no event, however, may a soly within the statutory minimum of the will apply and will expire SIX (6) MC e, cause the application to become A	reply be timely filed  rty (30) days will be considered timely.  NTHS from the mailing date of this communication.  BANDONED (35 U.S.C. § 133).				
1) Responsive to communication(s) filed on	·					
2a) This action is <b>FINAL</b> . 2b) ⊠ TI	his action is non-final.					
3) Since this application is in condition for allow closed in accordance with the practice under						
Disposition of Claims	annlication					
4) Claim(s) 1,37 and 51-56 is/are pending in the application.						
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected.						
6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to.						
8) Claim(s) 1, 37 and 51-56 are subject to restrict	ction and/or election requi	rement				
Application Papers	and and or orocator roqui	G. T.				
9) The specification is objected to by the Examine	er.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documen	ts have been received.					
2. Certified copies of the priority documen	ts have been received in	Application No				
<ul> <li>3. Copies of the certified copies of the price application from the International But See the attached detailed Office action for a list</li> </ul>	ureau (PCT Rule 17.2(a))					
14) Acknowledgment is made of a claim for domest	tic priority under 35 U.S.C	. § 119(e) (to a provisional application).				
<ul> <li>a)  The translation of the foreign language pr</li> <li>15)  Acknowledgment is made of a claim for domes</li> </ul>						
Attachment(s)						
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) Notice of	V Summary (PTO-413) Paper No(s)  f Informal Patent Application (PTO-152)				

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## **DETAILED ACTION**

## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to a native complement pathway protein modified such that the protein is capable of forming a down-regulation resistant C3 convertase, classified in class 530, subclass 380.
  - II. Claim 37, drawn to a DNA construct comprising a DNA sequence as defined in now cancelled claim 36, classified in class 536, subclass 23.1.
  - III. Claim 51, drawn to a method of reducing levels of complement pathway protein in a mammal, classified in class 424, subclass 184.1.
  - IV. Claim 52, drawn to a method of treating transplant rejection in a mammal, classified in class 424, subclass 184.1.
  - V. Claim 53, drawn to a method of localizing and/or amplifying endogenous complement protein conversion and deposition at a specific site, classified in class 424, subclass 184.1.
  - VI. Claim 54, drawn to a method of reducing complement-mediated destruction or damage to transplanted tissue organs, classified in class 424, subclass 184.1.
  - VII. Claim 55, drawn to a DNA sequence coding for a modified human C3 protein which is capable of forming a stable C3 convertase, classified in class 536, subclass 23.5.
  - VIII. Claim 56, drawn to a DNA construct comoprising a DNA sequence as defined in claim 51, classified in class 536, subclass 23.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II, VII and VIII are unique products. Group I is distinct from Groups II, VII and VIII because Group I encompasses proteins while Groups II, VII and VIII encompass DNA. DNA and proteins differ with respect to their physicochemical properties and are therefore patentably distinct. Groups II, VII and VIII all encompass DNA, but are unique products because only Group VII is defined in the instant claims. Group II depends from a cancelled claim (claim 36) and Group VIII lacks antecedent basis in claim 51 for the recited DNA molecule. Therefore Groups I, II, VII and VIII are patentably distinct.

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Groups III-VI are unique methods. They differ with respect to their respective endpoints, and are therefore patentably distinct, each from the other.

Group I and III-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the present case, the product as claimed, the modified native complement pathway protein can be used as an immunogen in a method of producing antibody secreting hybridomas, as well as in a method of reducing levels of complement pathway protein in a mammal, or in a method of treating transplant rejection in a mammal, or in a method of localizing and/or amplifying endogenous complement protein conversion and deposition at a specific site, or in a method of reducing complement-mediated destruction or damage to transplanted tissue organs.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search in the non-patent literature of any of these distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

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Amy DeCloux, Ph.D., Patent Examiner, September 8, 2002 Patrick J. Nolan, Ph.D., Primary Patent Examiner,